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Frank C. Fisenschenk, Ph.D. Patent Attorney

INFORMATION DISCLOSURE STATEMENT

Examining Group 1614 Patent Application Docket No. ISI-101 Serial No.10/561.411

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1614

Applicants : Andrew Bushell, Kathryn Wood, Mahzuz Karim, Vanessa Oliveira, Brigit

Sawitzki

Serial No. : 10/561,411

Filed: December 19, 2005

Conf. No. : 1086

For : Suppression of Transplant Rejection

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record. Applicants respectfully assert that the substantive provisions of 37 C.F.R. §§ 1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.

Patent Attorney Registration No. 45,332

Phone No.: 352-375-8100 Fax No.: 352-372-5800 Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/gyl/sl

Attachments: Form PTO/SB/08; copies of references cited therein.

Substitute for form 1449A/PTO				Complete if Known			
INCOR.				Application Number	10/561,411		
	MATION DISCL			Filing Date	December 19, 2005		
SIAIE	VIENT BY APP	LIC	ANI	First Named Inventor	Andrew Bushell		
	(use as many sheets	as nec	essary)	Art Unit	1614		
				Examiner Name			
Sheet	1	of	2	Attorney Docket Number	ISI-101		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Foreign Patent Document  Country Code 3 - Number 4 - Kind Code 5 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	F1	WO 90/15152 A	12-13-1990	Cobbold et al.	All	
	F2	EP 0 240 344 A	10-07-1987	Wellcome Found	All	
	F3	WO 01/00679 A	01-04-2001	lwakoshi et al.	All	
	F4	WO/ 01/68134 A	09-20-2001	Genetics Inst.	All	
	F5					
	F6					
	F7					

- 1	Examiner	Date
	Signature	Considered

"EXAMINET: Inflal if reference considered, whether or not citation is in conformance with MPEP 690. Draw line through citation if not in conformance and not considered include copy of this form with next communication to applicant." Applicants insulice clation designation number (pollonis See Kind Cotes of USPTO Patent Documents at <a href="https://www.uspto.gog.or.university.or.not/">https://www.uspto.gog.or.university.or.universit

This collection of information is required by 37 CFR 1 97 and 1 58. The information is required to obtain or retain a benefit by the public which is to fit and by the USPTO deproses, an application. Conferentially is operand by 38 USF, 122 and 37 CFR 1 14. This collection is estimated to base 1 loans to compete including gathering, preparing, and submitting the completed application form to the USPTO. There will vary depending upon the individual cost, and on the amount of time you required to complete his form andors suggestions for reducing his business, and the complete to the Chief information Officer, USP pattern and Trademark Office, P.O. Box 1450. Alexandria, VA. 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 4450. Alexandria, VA. 22313-1450.

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## Substitute for form 1449B/PTO

Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

Complete if Known			
Application Number	10/561,411		
Filing Date	December 19, 2005		
First Named Inventor	Andrew Bushell		
Group Art Unit	1614		
Examiner Name			
Attorney Docket Number	ISI-101		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, senal, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²	
	R1	TAYLOR, P. A. et al. "CD4"CD25" immune Regulatory Cells are Required for Induction of Tolerance to Alloantigen Via Costimulatory Blockade", <i>J. Exp. Med.</i> , June 4, 2001, pp. 1311-1317, Vol. 193, No. 11.		
	R2	QIN, S. et al. "Induction of Tolerance in Peripheral T Cells with Monoclonal Antibodies", European Journal of Immunology, 1990, pp. 2737-2745, Vol. 20, No. 12.		
	R3	KINGSLEY, C. I. et al. "CD25" CD4" Regulatory T Cells Prevent Graft Rejection: CTLA-4- and IL-10-Dependent Immunoregulation of Alloresponses ", Journal of Immunology, February 1, 2002, pp. 1080-1086, Vol. 168, No. 3.		
	R4	WALDMANN, H. et al. "How do Monoclonal Antibodies Induce Tolerance? A Role for Infectious Tolerance?", Annual Review of Immunology, 1998, pp. 619-644, Vol. 16.		
	R5	TAYLOR, P. A. et al. "The Infusion of Ex Vivo Activated and Expanded CD4*CD25* Immune Regulatory Cells Inhibits Graft-Versus-Host Disease Lethality", <i>Blood</i> , May 15, 2002, pp. 3493-3499, Vol. 99. No. 10.		
	R6	TAYLOR, P. A. et al. "Tolerance Induction of Alloreactive T Cells Via Ex Vivo Blockade of the CD40 CD40L Costimulatory Pathway Results in the Generation of a Potent Immune Regulatory Cell", <i>Blood</i> , June 15, 2002, pp. 4601-4609, Vol. 99, No. 12.		
	R7	FALCONE, M. et al. "A T helper cell 2 (Th2) Immune Response against Non-self Antigens Modifies the Cytokine Profile of Autoimmune T Cells and Protects against Experimental Allergic Encephalomyelitis" <i>J. Exp. Med.</i> , March 3, 1997, pp. 901-907, Vol. 184, No. 5.		
	R8	BENJAMIN, R.J. et al. "Induction of tolerance by monoclonal antibody therapy" Nature, April 3, 1986, pp. 449-551, Vol. 320.		
	R9			
	R10			
	R11			
	R12			

Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is quale as check mark here if English language Translation is stached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain to obtain or retain tify the public which is to file (and by the USPTO to process) an application. Confidentially is governed by 38 U.S. Of 123 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application from to the USPTO. Time will vary depending upon the individual case. Any comments of the amount of time you require to complete his form and/or suggestions for reform, should be sent to the Chef Information Officer, U.S. Pattern amount of time you require to complete his form and/or suggestions for reform, should be sent to the Chef Information Officer, U.S. Pattern and Trademark. Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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